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Insight Millennium III

510(k) Summary

Submitted by:

Company Name:	Fasstech
Company Address #1:	76 Treble Cove Road, #2
Company Address #2:	North Billerica, MA 01862
Contact Person:	Lee Brody
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Submitted on: September 25, 2002

Section 1: Device Name

Common or Usual Name: Electromyograph, Diagnostic
Proprietary Model Name: Insight Millennium III

Section 2: Indications for Use

- To measure bilateral differences in surface EMG along the spine
- To measure surface EMG along the spine during functional tasks
- To measure bilateral differences in skin temperature along the spine
- To measure Range of Motion of the three spinal regions
- To measure patient self-reported pressure sensitivity in joints and muscles
- To measure Heart Rate
- To chart patient progress during the course of treatment

Section 3: Device Description

The Insight Millennium III is a non-invasive, multi-modality physiologic monitoring device. The Insight Millennium III contains the following five sensor types: (1) surface EMG used to measure muscle activity, (2) infrared temperature sensor used to measure skin temperature, (3) inclinometer used to measure end-point range of motion, (4) algometer used to measure patient self-reported pressure sensitivity, and (5) heart rate sensor to measure heart rate.

Hardware
The Insight Millennium III hardware consists of an instrument console and five different sensor types. All five sensor types plug directly into the front panel of the Insight Instrument Console. The Insight Millennium III Instrument Console is powered via a UL2601 listed power supply. The Instrument Console is connected to a personal computer (IBM compatible) via an isolated USB port connection.

Software
The Insight Millennium III software displays real-time surface EMG, spinal Range of Motion, skin temperature, pressure, and heart rate readings, allowing the user to ensure that readings are stable prior to data collection. The Insight Millennium software allows the user to: (1) enter patient information, (2) record surface EMG, spinal Range of Motion, skin temperature, pressure and heart rate readings, (3) graph surface EMG, spinal Range of Motion, skin temperature, pressure and heart rate readings, and (4) print out reports.

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Section 4: Predicate Device

This section documents the substantial equivalence of the Insight Millennium III to legally marketed devices. Specifically, this section documents the substantial equivalence of Insight Millennium III to the following three products:

Manufacturer	Predicate Device Name	510(k) Number
Insight Millennium Plus	Fasstech	K011964
Medac System/3	Davicon	K914925

The Insight Millennium III is equivalent to these legally marketed devices in the following ways:

- The physical characteristics and electrical characteristics (performance characteristics) of the Insight Millennium III are equivalent to the Insight Millennium Plus. The only difference is the addition of a fifth sensor type, the Insight Heart Rate Sensor.
- The physical characteristics and electrical characteristics (performance characteristics) of the Insight Millennium Heart Rate Sensor is equivalent to the Medac System/3 heart rate sensor

The Insight Millennium III differs from these legally marketed devices in the following ways:

- The device types listed above have been combined for reasons of user convenience.

This section documents the substantial equivalence of the Insight Millennium III to legally marketed devices. The Insight Millennium III is a modest expansion of the Insight Millennium Plus, a device that we have previously registered with FDA. The Insight Millennium III differs from the Insight Millennium Plus in the following manner:

1. Hardware: Addition of a new sensor, The Insight Heart Rate Sensor. The Insight Millennium III Instrument Console is identical to that of the Insight Millennium Plus Console, including patient isolation and PC connection.

2. Software: The Insight Millennium III software is extended to include the Insight Heart Rate Sensor.

Predicate Device Comparison Chart

Feature	**Insight Millennium III**	Insight Millennium Plus	Medac System/3
Four Channels of surface EMG	**Yes**	Yes	N/A
Skin Temperature measurement via infrared thermal scanner	**Yes**	Yes	N/A
Range of Motion	**Yes**	Yes	N/A

Sensor			
Algometer	**Yes**	Yes	N/A
UL-2601 listed power supply	**Yes**	Yes	N/A
Heart-rate measure using IR Phethsmograph	**Yes**	N/A	Yes

Section 5: Performance Specification

The Insight Millennium III specifications are summarized below:

EMG

Electrodes:	4 ea. Smart Sensors with low-noise preamplifiers integral to electrode assemblies
Calibrated Range:	0.1 – 999 uV
Input Bias Current:	Less than 2.0 Picoamperes
Differential Input Impedance:	Greater than 1,000,000 Megaohms
Common Mode Rejection:	150 dB
Bandwidth:	20-500 Hz (50/60 Hz notch)
Noise:	Less than 0.1 uV (inputs shorted)
Detector:	Log power detector, 250 mS averaging filter.
Controls:	None

Range of Motion

Range:	360 degrees
Accuracy:	+/- 1 degree nominal
Controls:	Enter and Skip Buttons
Physical:	Case Material: Impact resistant, flame retardant ABS. 3.4"H x 3.5"W x 1.25"D. Weight 6.5 oz.

Temperature

Calibrated Range:	55°F - 120°F
Accuracy:	±0.2°F nominal
Sensors:	Two thermopile, fixed 2.5" apart (center-to-center)
Controls:	Enter button
Physical:	Case Material: Impact-resistant, Aluminum with 0.5" ABS Plastic Outer Ring.
Size:	5.5"L x 3.5"W x 2.5"H. Weight 15 oz.

Algometer

Calibrated Range:	0-100 lbs.
Accuracy:	±3% nominal

Contact Area:	1.0 cm^2
Sensor:	One pressure transducer attached to a stiff rod.
Controls:	Enter button
Physical:	Case Material: Impact-resistant, Aluminum with 3.0" ABS Plastic Stiff Rod.
Size:	5.5"L x 1.75"W x 2.5"H. Weight 9 oz.

Heart Rate Sensor

Sensor Type	IR Plethsmograph (attached to finger with Velcro)
Output Voltage:	5 – 50 mV, typical at rest
Output Impedance:	1 kΩ, nominal
Weight:	28 grams
Sensor Size:	15 x 15 x6.3 mm

Instrument Console

Inputs:	4 each EMG electrodes 1 each inclinometer 1 each temperature sensor 1 each algometer sensor 1 each Heart Rate sensor
Output:	Isolated USB
A/D converter:	16 bit, 16 channel
Controls:	None
Power:	12V, 500 mA UL-2601 listed power supply.
Physical:	Case Material: Impact resistant, flame retardant ABS. 3.5"H x 8.375"W x 9"D. Weight 3 lbs. 11 oz.

Section 6: Patient Safety

The Insight Millennium III patient isolation is assured by the following two electrical isolation barriers:

1. Medical-Grade Universal Power Supply: This device is a UL2601 compliant AC line to 12 VDC, 28 W converter. This internal power supply is partitioned from all other circuitry via an earthed steel chassis. The power supply accepts 85-264 VAC, and 47-63 Hz via an IEC 60320 fused input module.

   This supply provides low-level isolated power to the Non-Patient Side of the Insight Millennium III circuitry, as well as power to the DC-to-DC isolation converter that powers to the Patient Side (see #2 below).

2. DC-to-DC Patient Isolation Converter: This converter is a UL2601 compliant DC-to-DC converter, and meets the dielectric withstand and leakage current requirements of the UL2601 standard for Patient Care Equipment with isolated patient leads.

This converter supplies all power to patient-applied parts and related circuitry. Each of the direct patient-applied parts have individual current limiters for fault condition.

In addition, the Patient Side of the Insight Millennium III is isolated from the host PC as follows:

3. Optically Isolated Data Link: Signals are converted from analog voltages to 16 bit digital values by the analog-to-digital converter (ADC). The digital data is sent to and from the USB of the PC across an optically isolated data link.

   This optical link is UL2601 compliant, providing the dielectric withstand and low leakage current characteristics specified in UL2601.

Section 7: Conclusion

The Insight Millennium III is substantially equivalent to the predicate devices. Furthermore, the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Mr. Lee Brody
Chief Operating Officer
Fasstech
76 Treble Cove Road, Bldg. #2
North Billerica, Massachusetts 01862

Re: K023209
Trade/Device Name: Insight Millennium III
Regulation Number: 21 CFR 890.1375, 882.5050
Regulation Name: Diagnostic electromyography, Biofeedback device
Regulatory Class: II
Product Code: IKN, HCC
Dated: September 5, 2003
Received: September 9, 2003

Dear Mr. Brody:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023209

Device Name: Insight Millennium III

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023209